

EXHIBIT 8

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

| | | |
|---|---|--------------------------------------|
| NATIONAL ASSOCIATION OF CHAIN DRUG STORES and |) | |
| |) | |
| NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, |) | Civil Action No. 1:07-cv-02017 (RCL) |
| |) | |
| Plaintiffs, |) | |
| v. |) | |
| |) | |
| UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES <i>et al.</i>, |) | |
| |) | |
| Defendants. |) | |

**PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION
AND REQUEST FOR EXPEDITED HEARING**

Pursuant to Fed. R. Civ. P. 65(a) and LCvR 7(f), 65.1(c) and 65.1(d), Plaintiffs National Association of Chain Drug Stores and National Community Pharmacists Association, through counsel, respectfully request that this Court (1) hold an expedited hearing on Plaintiffs' Motion for Preliminary Injunction and (2) enter a preliminary injunction enjoining Defendants, the Department of Health and Human Services ("HHS"); Michael O. Leavitt, Secretary of HHS, in his official capacity; the Centers for Medicare and Medicaid Services ("CMS"), and Kerry Weems, the Acting Administrator of CMS, as follows:

- a. From undertaking any and all agency action to implement the AMP Rule, which was published in the Federal Register on July 17, 2007 (71 Fed. Reg. 39142), including, but not limited to, posting AMP data calculated under the AMP Rule on a public website and using AMP data calculated under the AMP Rule as the basis to reimburse pharmacies under Medicaid;
- b. From including the following transactions in the calculation of AMP as these transactions fail to satisfy all the statutory elements of AMP, which is defined as

“the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade,” 42 U.S.C.

§ 1396r-8(k)(1):

- i. Direct sales to patients;
 - ii. Sales to physicians;
 - iii. Sales to retail pharmacies;
 - iv. Sales to hospital pharmacies, clinics, and affiliated entities;
 - v. Sales to other manufacturers;
 - vi. Sales to medical outpatient facilities;
 - vii. Sales to home infusion providers;
 - viii. Specialty pharmacy sales;
 - ix. Sales to home health providers;
 - x. Sales to mail order pharmacies;
 - xi. Sales and Rebates To PBMs;
 - xii. GPO Fees;
 - xiii. Nominal Price Sales To “Any Entity”;
 - xiv. Rebates and Discounts “Associated With” Sales;
 - xv. Sales Reimbursed By Third Parties; and
 - xvi. Low Income Patient Programs;
- c. From applying FULs in a state unless the drug products used to calculate the FUL are “generally available to the public through retail pharmacies in the State,” regardless of whether or not the drugs are available nationally; and
- d. From applying AMP-based FULs to B-rated, not equivalent, drugs when AMPs are only to be applied to A-rated, or equivalent, drugs.

Should this unlawful regulation be permitted to be implemented, community retail pharmacy members of Plaintiffs National Association of Chain Drug Stores and National Community Pharmacists Association will suffer irreparable injury. Further, disadvantaged Americans served by pharmacies pursuant to Medicaid may find access to their local pharmacy reduced or even eliminated. Defendants will not be harmed by a delay in implementing an unlawful rule.

An expedited hearing is essential, pursuant to LCvR 65.1(d), due to a recent suggestions by Defendant CMS that it will release the flawed AMP data generated from its unlawful AMP Rule on a public website well before the new year. Indeed, as reflected in the attached Declaration of Mary Ann Wagner, R. Ph., of Plaintiff National Association of Chain Drug Stores, Defendant CMS contemplates posting the flawed AMP data *in approximately one month*. See Exhibit 1, Declaration of Mary Ann Wagner, ¶ 5 (reviewing comments by Defendant CMS on its “plan” to post the AMP data calculated under the new AMP Rule as early as mid-December). Once the flawed data based on the unlawful AMP Rule is publicly posted on the internet, its damage will be far-reaching and irreversible. See Memorandum of Points and Authorities in Support of Plaintiffs’ Motion for Preliminary Injunction at I.B.7 (referring to Dr. Schondelmeyer’s conclusions on how harmful public posting of the AMP data will be)(internal citations omitted). For that reason, Plaintiffs respectfully request that the Court set a hearing date of no later than twenty (20) days from the date of this filing or Wednesday, December 5, 2007. See LCvR 65.1(d).

In further support of this Motion and its request for an expedited hearing, Plaintiffs respectfully refer the Court to the attached Memorandum of Points and Authorities.

The undersigned certifies that consent to this Motion could not be obtained from opposing counsel pursuant to LCvR 7(m) because opposing counsel has not yet been identified by Defendants.

WHEREFORE, Plaintiffs request that their Motion for Preliminary Injunction be granted.

Dated: November 15, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 15th day of November, 2007, true copies of the foregoing Plaintiffs' Motion For Preliminary Injunction, Memorandum in support thereof and proposed Order were served via certified mail, return receipt requested, postage pre-paid on the following:

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

**NATIONAL ASSOCIATION OF CHAIN
DRUG STORES and NATIONAL
COMMUNITY PHARMACISTS
ASSOCIATION,**

Plaintiffs,

v.

**UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES *et al.*,**

Defendants.

Civil Action No. 1:07-cv-02017 (RCL)

**MEMORANDUM OF THE NATIONAL ASSOCIATION OF
CHAIN DRUG STORES AND NATIONAL COMMUNITY
PHARMACISTS ASSOCIATION IN SUPPORT OF THEIR MOTION FOR
PRELIMINARY INJUNCTION AND REQUEST FOR EXPEDITED HEARING**

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INTRODUCTION

This case involves a final rule promulgated by the Secretary of the Department of Health and Human Services (“HHS”), through the Centers for Medicare and Medicaid Services (“CMS”), that totally disregards the plain language of the Social Security Act, Congress’ clear intent when it enacted that statutory language, the Defendants’ prior application of that statutory language, dozens of federal and State statutes and regulations, longstanding industry practice, and common sense.

The final rule, which is known as the “AMP Rule,” requires drug manufacturers to calculate an “average manufacturer price” (or “AMP”) for each of their drug products. The AMP Rule will use AMP to establish Federal Upper Limits on reimbursement for generic drugs in the Medicaid program. 72 Fed. Reg. 39142 (July 17, 2007) (A copy of the AMP Rule with Preamble is attached as Exhibit A).

The AMP Rule violates the Social Security Act in at least three ways.

First, Section 1927 of the Social Security Act defines “average manufacturer price”, in pertinent part, as “the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.” 42 U.S.C. § 1396r-8(k)(1). However, the AMP Rule includes a significant number of transactions that do not belong in the calculation of AMP because they are not prices paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade. Examples of transactions improperly included in the AMP Rule are sales directly to patients; sales to physicians; sales at nominal price to “any entity”; sales to surgical centers; sales to dialysis centers; sales to mental health centers; sales to home health care providers; sales to home infusion providers; sales to clinics; sales to hospital outpatient pharmacies or a hospital “affiliated entity”; sales to pharmacy benefit managers (“PBMs”); and sales to mail order pharmacies. *See* AMP Rule § 447.504(g).

In addition, the AMP Rule completely reverses the statutory test for AMP by requiring a manufacturer to include *virtually all* prices in AMP unless the manufacturer has “adequate documentation” which proves that the price should be excluded.

Second, the AMP Rule also does not comply with the Social Security Act’s requirements for establishing Federal Upper Limits on reimbursement for multiple source drugs. The statute provides that the Defendants may not apply a Federal Upper Limit in a State unless the drug products used to calculate that Federal Upper Limit are “generally available to the public through retail pharmacies in the State.” 42 U.S.C. § 1396r-8(k)(7). The AMP Rule ignores this requirement.

Third, the AMP Rule violates the statute by applying Federal Upper Limits to drug products that are not “therapeutically equivalent” to the drug products that were used to calculate those Federal Upper Limits. 42 U.S.C. § 1396r-8(k)(7).

In addition to using the flawed AMPs to calculate Federal Upper Limits on Medicaid reimbursement for generic drugs, CMS will publish flawed AMPs for all drugs (brand and generic) on a public website. Posting misleading data on a public website will cause further harm to retail pharmacies and the public at large.

The Defendants failed to implement the plain meaning of the Social Security Act because they were motivated to cut billions of dollars from payments to retail pharmacies that serve disadvantaged Americans through the Medicaid program. Medicaid reimbursement rates for retail pharmacies were expected to decline as a result of the Deficit Reduction Act of 2005. However, in their zeal to cut retail pharmacy reimbursement rates even further, the Defendants have slashed reimbursement well below the rates intended by Congress. Retail pharmacies will suffer even greater losses than they would if the Defendants had faithfully implemented the plain meaning of the statute.

CMS estimates that the AMP Rule will reduce Medicaid reimbursement to retail pharmacies by more than \$8 billion over five years. Government studies have found that reimbursement for drugs will be cut well below the prices that retail pharmacies pay for drugs. See *OIG, Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program*, OEI-03-06-00400 (June 2007) (A copy of which is attached as Exhibit B); GAO, *Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs*, GAO-07-239R (Dec. 22, 2006). (A copy is attached as Exhibit C).

Many retail pharmacies, particularly pharmacies in urban and rural areas that serve a large number of Medicaid patients, will be forced to reduce hours and services, forced out of the Medicaid program, or forced to close their doors altogether. Medicaid patients will lose access to retail pharmacies they rely on for critical pharmacy and pharmacist care. The expert retained by the Plaintiffs estimates that, as a result of the AMP Rule, “the retail pharmacy market may see the loss of 10,000 to 12,000 pharmacies (the vast majority of which would be pharmacies in rural or inner city urban areas and with high Medicaid volumes) over the next few years.” Expert Report of Stephen W. Schondelmeyer, Pharm.D., Ph.D. dated November 13, 2007 (“Schondelmeyer Report”), ¶31. (A copy of the Schondelmeyer Report is attached as Exhibit D.)¹

This Court should grant the motion for a preliminary injunction because:

¹ The National Association of Chain Drug Stores (“NACDS”) and the National Community Pharmacists Association (“NCPA”) have moved this Court, concurrently with the filing of the Motion for a Preliminary Injunction for an Order allowing NACDS and NCPA to supplement the Administrative Record with Dr. Schondelmeyer’s Report to assist the Court with technical aspects of the pharmaceutical market place and provide an analysis of the economic impact of the AMP Rule.

- The Plaintiffs are likely to succeed on the merits of their case:
 - The AMP Rule is contrary to the plain language and definition of AMP in the Social Security Act, because the AMP Rule includes in AMP transactions that are not prices paid to manufacturers by wholesalers for drugs distributed to retail pharmacies;
 - The AMP Rule disregards the statutory requirement that Federal Upper Limits on reimbursement may be based only on drug products that are generally available to the public through retail pharmacies in each State; and
 - The AMP Rule fails to comply with the statutory requirement that Federal Upper Limits may only be applied to drugs that are therapeutically equivalent;
- The AMP Rule will cause irreparable harm to retail pharmacies, Medicaid patients and the public because an estimated 10,000 to 12,000 pharmacies are expected to be forced to reduce their hours, refuse Medicaid beneficiaries, or close their doors;
- The Defendants will not be harmed if the AMP Rule is delayed; and
- The public interest will be served by a preliminary injunction that requires the Defendants to abide by the laws and protects public access to retail pharmacies.

FACTUAL BACKGROUND

Plaintiffs NACDS and NCPA are non-profit trade associations that represent over 55,000 community retail pharmacies. Retail pharmacies dispense prescription medications to millions of needy Americans through the Medicaid program.

Medicaid is a joint federal and State program that was created by the Social Security Act to provide health care to disadvantaged Americans. 42 U.S.C. § 1396. Federal and State government agencies share responsibility for funding the Medicaid program. 42 U.S.C. § 1396b. The Medicaid program is administered by each State in accordance with a Medicaid State Plan that is reviewed and approved by the Defendants. 42 U.S.C. § 1396a. States must comply with federal requirements specified in the Social Security Act, as well as the regulations and program guidance issued by the Defendants pursuant to the Social Security Act. 42 U.S.C. § 1396c.

Retail pharmacies dispense prescription drugs to patients who are covered by the Medicaid program. In return, retail pharmacies receive reimbursement from the Medicaid program. The amount of reimbursement varies, depending in part upon whether a retail pharmacy dispenses a single source drug or a multiple source drug. Single source drugs are commonly referred to as brand name drugs, and multiple source drugs are commonly referred to as generic drugs.

The Social Security Act requires the Defendants to calculate Federal Upper Limits on Medicaid reimbursement to retail pharmacies that dispense multiple source drugs to Medicaid patients. The Federal Upper Limits place an overall cap, or ceiling, on the amount that State Medicaid programs may pay retail pharmacies for multiple source drugs that are dispensed to Medicaid patients. 42 U.S.C. § 1396r-8.

Since the early 1990s, drug manufacturers have paid rebates to State Medicaid programs for drugs dispensed to Medicaid patients. Pursuant to the Social Security Act, these rebates are based on the AMP paid to the manufacturer by wholesalers for the drugs distributed to the retail pharmacy class of trade. Drug manufacturers calculate AMPs for each of their drug products, and report the AMPs to the Medicaid program on a regular basis. *See id.*, originally enacted by the Omnibus Budget Reconciliation Act of 1990, Pub. L. 101-508.

The Deficit Reduction Act of 2005, Pub. L. 109-171 (the “DRA”) amended the Social Security Act to require the Defendants to use AMP also as the basis for setting Federal Upper Limits on reimbursement for multiple source drugs. The Social Security Act statutorily defines AMP and “multiple source drug.” *See* Social Security Act § 1927 (42 U.S.C. § 1396r-8), as amended by DRA § 6001.

In response to the DRA, the Defendants promulgated the AMP Rule on July 17, 2007. The AMP Rule substantially revises the method of calculating AMPs and the method of establishing Federal Upper Limits on reimbursement for multiple source drugs.

CMS has indicated that the AMP website may be publicly posted at any time. The reimbursement cuts imposed on retail pharmacies by the AMP Rule will begin in January 2008.²

ARGUMENT

When deciding whether to grant a preliminary injunction, the Court examines whether (1) there is a substantial likelihood the plaintiffs will succeed on the merits; (2) plaintiffs will be irreparably injured if an injunction is not granted; (3) an injunction will not substantially injure the defendants; and (4) the public interest will be furthered by the injunction. *Ellipso, Inc. v. Mann*, 480 F.3d 1153, 1157 (D.C. Cir 2007) (upholding preliminary injunction issued by this Court). The Court balances the factors, and “[i]f the arguments for one factor are particularly strong, an injunction may issue even if the arguments in other areas are rather weak.” *Id.*, (quoting *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1318 (D.C. Cir. 1998)).

As discussed below, the Plaintiffs have a substantial likelihood of success on the merits of their claims, the retail pharmacies represented by the Plaintiffs will suffer irreparable harm absent an injunction, the Defendants will not be harmed by an injunction, and an injunction is in the public interest.

I. The Plaintiffs are Likely to Succeed on the Merits.

A. The Standard of Review Under *Chevron*

² The Plaintiffs consider litigation a last resort, and therefore did not immediately file suit when the AMP Rule was promulgated. Instead, since July 2007, the Plaintiffs have advocated aggressively for enactment of legislation that would reign in the Defendants’ excesses and eliminate the need for litigation. *See* The Fair Medicaid Drug Payment Act (S. 1951 and H.R. 3700) and The Saving Our Community Pharmacies Act (H.R. 3140). However, due to the implementation schedule established by CMS, the Plaintiffs must act now to protect their legal rights.

The AMP Rule is subject to review under the standards set forth in *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837 (1984). A *Chevron* analysis involves a two-step process. Under *Chevron* Step I, the Court asks “whether Congress has directly spoken to the precise question at issue.” *Chevron*, 467 U.S. at 842; *see also Public Citizen, Inc. v. HHS*, 332 F.3d 654, 659 (D.C. Cir. 2003). If Congress has spoken, then that is the end of the analysis, and the Court “must give effect to the unambiguously expressed intent of Congress.” *Chevron*, 467 U.S. at 843; *see also Northpoint Tech., Ltd. v. FCC*, 412 F.3d 145, 151 (D. C. Cir. 2005) (*quoting Chevron*). No deference is shown to the Defendants under this step. *See Shays v. FEC*, 508 F. Supp. 2d 10, 30 (D.D.C. 2007).

If the word or phrase is defined in the statute, or elsewhere in the United States Code, that definition governs if applicable in the context used. *Colautti v. Franklin*, 439 U.S. 379, 392 (1979). Even if the word or phrase is not defined by statute, it may have an accepted meaning in the area of law addressed by the statute. *See, e.g., Sullivan v. Stroop*, 496 U.S. 478, 483 (1990) (phrase “child support” as used in Title IV AFDC provisions of Social Security Act had accepted meaning in area of law addressed by statute); *see also Miles v. Apex Marine Corp.*, 498 U.S. 19, 32 (1990) (“We assume that Congress is aware of existing law when it passes legislation”). In these situations, the accepted meaning governs, and the word or phrase is considered a technical term or “term of art” and Congress’ use of those terms in a statute “may be taken as satisfaction with widely accepted definitions, not as a departure from them.” *Morissette v. United States*, 342 U.S. 246, 263 (1952).

Reliance on expert definitions of terms or terms of art is a sound “general rule of construction.” *Massachusetts v. Blackstone Valley Elec. Co.*, 67 F.3d 981, 986 (1st Cir. 1995); *see also Corning Glass Works v. Brennan*, 417 U.S. 188, 201 (1974) (“[W]here Congress has

used technical words or terms of art, ‘it [is] proper to explain them by reference to the art or science to which they [are] appropriate.’”)

The AMP Rule fails the *Chevron* Step I test because it does not conform to the plain language of the Social Security Act in three separate ways:

- First, the AMP Rule includes in AMP calculations many transactions, such as sales to patients and physicians, that are not “prices paid to manufacturers” by “wholesalers” for “covered outpatient drugs” distributed to the “retail pharmacy class of trade”;
- Second, the AMP Rule ignores the statutory language that limits the definition of a multiple source drug to drug products that are “generally available to the public through retail pharmacies in the State”; and
- Third, the Defendants apply Federal Upper Limits to drug products that are not “therapeutically equivalent,” in direct contravention of the statutory language.

The AMP Rule also fails *Chevron* Step II. Under this analysis, the Court may defer to the Defendants’ application of the statute, but only if it is a permissible and reasonable “construction of the statute.” *Chevron*, 467 U.S. at 844; *Public Citizen*, 332 F.3d at 659; *Southern Cal. Edison Co. v. FERC*, 116 F.3d 507, 511 (D.C. Cir. 1997) (deference is owed to an agency only if its construction is “reasonable” in light of the statutory text, history and purpose). Additionally, a Court must set aside a rule if it is “arbitrary, capricious, . . . or otherwise not in accordance with the law.” 5 U.S.C. § 706(2)(A).

For example, in *Samaritan Health Service v. Bowen*, 811 F.2d 1524, 1528 (D.C. Cir. 1987), the D.C. Circuit referred to other agency regulations, industry terminology, and other court rulings to determine that the Secretary of HHS’ interpretation of the word “nurseries” in agency regulations was arbitrary and capricious. *See also Shays*, 508 F. Supp. 2d at 12 (finding agency rule arbitrary and capricious because it lacked an explanation for why it reversed an earlier agency position and how the new regulation would fulfill its function). An interpretation

cannot survive an unarticulated, erroneously based or irrational reason for that interpretation.

See Shays, 508 F. Supp. 2d at 31-32.

The AMP Rule is arbitrary and capricious because “it is so implausible that it could not be ascribed to a difference in view or a product of agency expertise.” *See Motor Vehicle Mfrs. Ass’n. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42-43 (1983). As discussed below, it is simply unreasonable for the AMP Rule to conclude that patients, physicians, mental health centers, surgical centers, dialysis centers, home health care providers, home infusion providers, and many other entities are “wholesalers” and “retail pharmacies.” The AMP Rule is also internally contradictory and inconsistent with the Defendants’ prior and existing definitions of terms such as “wholesaler” and “retail pharmacy.” The AMP Rule is arbitrary and capricious because it is contrary to the Defendants’ prior application of the statute, contrary to dozens of other federal and State statutes and regulations, contrary to industry practice, and contrary to common sense.

B. The AMP Rule Violates the Plain Language of the Statute’s Definition of AMP.

The statutory definition of AMP is clear and simple: AMP is the average price paid to manufacturers by wholesalers for drugs distributed to retail pharmacies. The Social Security Act provides in relevant part that “the term ‘Average Manufacturer Price’ means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.” 42 U.S.C. § 1396r-8(k)(1).³

³ In full, AMP is defined as:

(1) Average manufacturer price.

(A) In general. Subject to paragraph (B), the term “average manufacturer price” means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.

The statute establishes a four-part test for determining whether a price may be included in AMP. First, only prices paid to drug manufacturers may be included in AMP. Second, those prices must be paid by drug wholesalers. Third, the purchased drugs must be distributed to the retail pharmacy class of trade. Fourth, the purchased drugs must be “covered outpatient drugs” (*i.e.*, drugs for which Medicaid will pay). Under the statute, a price must satisfy all four parts of the test before it may be included in AMP.

The AMP Rule violates the statute because it includes in AMP many transactions that have nothing to do with prices paid to manufacturers by wholesalers for covered outpatient drugs distributed to retail pharmacies. As examples, the AMP Rule improperly includes in AMP calculations sales to patients, physicians, surgical centers, dialysis centers, mental health centers, home health care providers, home infusion providers, clinics, and hospital pharmacies. Clearly these individuals and entities are not wholesalers, nor are they retail pharmacies. The AMP Rule also includes in AMP calculations rebates and fees paid by manufacturers which clearly are not prices paid to manufacturers. In addition, the AMP rule includes sales of many drugs that are not covered outpatient drugs.

Each of the four parts of the statutory AMP test are addressed in sections 1 through 4 below. Section 5 addresses specific examples of transactions that violate one or more parts of the statutory test.

1. “Price Paid to the Manufacturer.”

(B) Exclusion of customary prompt pay discounts extended to wholesalers. The average manufacturer price for a covered outpatient drug shall be determined without regard to customary prompt pay discounts extended to wholesalers.

(C) Inclusion of section 355(c) drugs. In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under section 355(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.S § 355(c)], such term shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to the retail pharmacy class of trade.
42 U.S.C. § 1396r-8(k)(1).

The meaning of “price paid to the manufacturer” is clear and unambiguous. *See* Schondelmeyer Report at ¶¶ 71-80. Payments by a manufacturer to a third party, or payments by a manufacturer for separate services, are not “prices paid to the manufacturer” for a drug. *Id.*

However, the AMP Rule includes in AMP calculations certain transactions that are not prices paid to manufacturers. The AMP Rule includes payments by manufacturers that do not reduce the prices paid by drug purchasers. The Defendants acknowledge that they include in AMP calculations certain payments by manufacturers to non-purchasers. The Defendants disagreed with the comment that only payments between manufacturers and “wholesalers” (which they define as virtually any purchaser) should be included in AMP calculations. *See* AMP Rule Preamble, 72 Fed. Reg. at 39165. The Defendants rationalize this approach as follows:

We recognize that the statute defines AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade; however, in light of our understanding of congressional intent, we believe that the definition is meant to capture discounts and other price adjustments, regardless of whether such discounts or adjustments are provided directly or indirectly by the manufacturer.

Id. at 39147. The true Congressional intent is reflected in the plain language that Congress used: AMP is the average “price paid to the manufacturer,” not prices paid by the manufacturer to non-purchasers.

2. “Wholesaler.”

Federal and State laws and regulations, as well as longstanding industry practices, define drug wholesalers as middlemen between manufacturers and providers who (1) are licensed by States as wholesalers, and (2) do not dispense drugs to consumers. Schondelmeyer Report at ¶¶ 84- 88.

First, State licensure is a crucial hallmark of a drug wholesaler. If the law does not require an entity to be licensed as a wholesaler, then as a matter of law that entity is not a

wholesaler. Federal law requires drug wholesalers to be licensed by the States. 21 U.S.C. § 353(e)(2)(A) (barring an entity from participating in wholesale distribution of prescription drugs unless licensed as a wholesaler by a State). That statute requires the Secretary of HHS to issue standards for State licensure of wholesalers, which the Secretary (through the FDA) promulgated in regulations. *See* 21 C.F.R. § 205.1 *et seq.* State wholesaler licensure standards consistently define “wholesaler” and require licensure of any entity engaged in “wholesale distribution.” *See* Schondelmeyer Report at ¶¶ 84, 86-87.

In two different programs applying the same AMP statute, HHS agrees that the word “wholesaler” includes only licensed wholesalers. Federal law requires the Secretary of HHS to apply the Social Security Act’s definition of AMP in the 340B program. *See* 42 U.S.C. 256b(a)-(b). The Secretary, acting through the Health Resources and Services Administration (“HRSA”), defines “wholesaler” as used in the definition of AMP to include only licensed wholesalers. *See* Pharmaceutical Pricing Agreement Between The Secretary of HHS and The Manufacturer (available at <ftp://ftp.hrsa.gov/bphc/pdf/opa/pricingagreement.pdf>; copy is attached as Exhibit E) (defining “wholesaler” for purposes of AMP as an entity “having a wholesale distributor’s license . . .”).

Similarly, HHS adopts this same definition of “wholesaler” in its AIDS Drug Assistance Program (“ADAP”). The ADAP program, which like Medicaid receives rebates from drug manufacturers based on AMP, defines “wholesaler” as it appears in the statutory definition of AMP to include only entities “having a wholesale distributor’s license, to which a manufacturer sells the covered outpatient drug....” *See* ADAP Manual (2003 Version), available at <http://hab.hrsa.gov/tools/adap/adapSecIChap1.htm> (web page attached as Exhibit F).

In contrast, despite the fact that the AMP Rule applies the exact same statutory AMP provision, the AMP Rule does not limit the definition of “wholesaler” to licensed wholesale

distributors. Instead, the AMP Rule's definition includes virtually all purchasers of drugs from manufacturers, even if they are physicians, patients or others who are not licensed as wholesalers. AMP Rule at § 447.504(f).

The Defendants acknowledge that the AMP Rule's definition of "wholesaler" contradicts the HRSA definition of wholesaler, even though both definitions apply the same AMP provision of the Social Security Act. *See* AMP Rule Preamble, 72 Fed. Reg. at 39224. Defendant CMS dismisses this contradiction and suggests that HRSA is a different agency, *see id.*, even though both CMS and HRSA are agencies within HHS and under the control of the Secretary and are interpreting the same statute. Thus one subsidiary of HHS is contradicting another subsidiary of HHS regarding this crucial definition.⁴

Second, another hallmark of a "wholesaler" is that it is a middleman between manufacturers and pharmacies or providers that does not dispense medications to patients. The "plain meaning" of "wholesaler" is "a merchant middleman that sells commodities in quantity to retail merchants." *Id.* at ¶ 89. Wholesalers are distinct from retailers who sell to end users. *Id.* at ¶ 90. Wholesalers do not, and in fact cannot, sell drugs to consumers. *Id.* at ¶¶ 87, 106.

These common and well-accepted dictionary definitions of "wholesaler" are reflected in long-standing drug industry practices. As a drug industry term of art, "wholesalers" are defined as "middle men who buy drugs from manufacturers and sell those drugs to pharmacies, providers, and other entities that in turn sell the drugs to the ultimate consumer." *Id.* at ¶ 91. This simple approach is used to determine what companies qualify to become members of the Healthcare Distribution Management Association, the national association for drug wholesalers. *Id.* at ¶ 92.

⁴ Importantly, it is the Secretary of HHS that promulgated these rules through the agencies under the Secretary's control.

This common sense definition of “wholesaler” is also reflected in federal statutes and regulations. Congress defines who qualifies as a drug wholesaler in the Food, Drug and Cosmetic Act. *See* 21 U.S.C. § 353(e)(2)(B) (defining “wholesale distribution” to exclude sales to consumers or patients). The Food and Drug Administration (“FDA”), a subsidiary of HHS, adopted a definition of “wholesale distribution” that reflects this common understanding of drug wholesalers. 21 C.F.R. § 203.3(cc).

In contrast, the AMP Rule considers patients, physicians, hospitals, retail pharmacies and virtually “any entity” that purchases drugs from a manufacturer to be a “wholesaler.” *See* AMP Rule at § 447.504(f). As discussed in section I.B.5 below, this definition includes many types of providers that cannot be wholesalers because they are not middlemen between manufacturers and pharmacies. Instead, many these entities dispense medications to patients, which wholesalers are not allowed to do. *See* Schondelmeyer Report at ¶ 87.

In sum, the AMP Rule’s definition of “wholesaler” is directly contrary to the plain meaning of the statute, contrary to other federal statutes and federal regulations, contrary to the Defendants’ own policies, contrary to every relevant State law and regulation, contrary to longstanding industry practices, and contrary to common sense. Dr. Schondelmeyer has provided a telling graphical comparison between the real world understanding of the term “wholesaler” and the artificial one created by CMS. *See* Schondelmeyer Report, Exhibits 3D and 3E.

3. “Retail Pharmacy Class of Trade.”

The “retail pharmacy class of trade” is clearly defined by federal and State statutes and regulations, and there is a common industry usage of this term of art. The plain meaning of “retail pharmacy” is well known and commonly understood. A retail pharmacy is an entity that

(1) is licensed as a retail pharmacy, (2) has a licensed pharmacist to dispense medications, and (3) serves the general public.

First, a retail pharmacy is an entity that must be licensed as such by a State. If an entity is not required to be licensed as a retail pharmacy, then as a matter of law it is not a retail pharmacy. Defendants define “retail pharmacy” in the Medicare drug program as limited only to “licensed” pharmacies. 42 C.F.R. § 423.100. Every State has a process for licensing entities as retail pharmacies, and all retail pharmacies must be licensed by a State. States license “retail pharmacies” as distinct from mail order pharmacies, hospital pharmacies, clinics, and other types of pharmacy or provider licenses. *See* Schondelmeyer Report at ¶¶ 105.

Second, pharmacies are where pharmacists work. Every State requires a retail pharmacy to have a licensed pharmacist. *See Id.* If an entity is not required to have a licensed pharmacist on staff, as a matter of law it is not a retail pharmacy. *See, e.g.,* D.C. Code § 47-2885.09; D.C. Mun. Regs., tit. 22, § 1909.1-2 (“A pharmacy shall be operated only by a licensed pharmacist”).

Third, a retail pharmacy must sell medications to the “general public.” A pharmacy serves the “general public” only if it is “accessible to all people in the community.” Schondelmeyer Report at ¶ 108. A retail pharmacy or other provider that serves only a subset of the populace does not serve the general public. *See Id.* at ¶¶ 109-110. For example, a mail order pharmacy or other provider that only serves members of particular health plans or particular patients does not serve the general public. *See* 42 C.F.R. § 423.100 (Defendants’ Medicare definition of “retail pharmacy” excludes mail order pharmacies and includes only pharmacies where a patient may purchase prescription drugs “without being required to receive medical services from a provider or institution affiliated with that pharmacy”). Likewise, a “specialty pharmacy,” dialysis center, home infusion provider, mental health center, or other provider that

specializes in serving a subset of the public does not serve the general public, and therefore, falls outside CMS' own definition. Schondelmeyer Report at ¶¶ 108, 163-64, 167, 170, 174.

The Defendants acknowledge that an entity is not a retail pharmacy unless it serves the "general public." *See* AMP Rule at § 447.504(e); AMP Rule Preamble, 72 Fed. Reg. at 39174. However, as discussed below in Section I.B.5, *infra*, the AMP Rule includes sales to many providers that are not retail pharmacies because they do not serve the general public. The Defendants' inclusion in the "retail pharmacy class of trade" of many entities that are not retail pharmacies is contrary to the plain meaning of the statute, contrary to the Defendants' own regulations and policies, contrary to longstanding industry and governmental practices, and is internally inconsistent with other provisions of the AMP Rule.

It is also important to emphasize that the "retail pharmacy class of trade" has a "specific structural meaning" in the pharmaceutical industry. Schondelmeyer Report at ¶¶ 112-13. The pharmaceutical industry clearly delineates between retail pharmacies and other types of pharmacies, such as mail order pharmacies. *Id.* at ¶ 38, 115. "Retail pharmacies" are defined as traditional chain and independent pharmacies, food and drug store pharmacies, and mass merchandisers with pharmacies. *Id.* at ¶ 114. The pharmaceutical industry does not consider mail order pharmacies, clinics, physicians, hospitals or others to be included in the retail pharmacy class of trade. *Id.* at ¶¶ 115-17. The retail pharmacy class of trade pays one set of prices for drugs, and mail order pharmacies and other providers pay a very different set of lower prices for the same drugs. *Id.* at ¶¶ 49-53.

The Defendants' use of the term "retail pharmacy class of trade" stands in "stark contrast" to the use of that term of art in the pharmaceutical market. *Id.* at ¶¶ 25, 112-118. Dr. Schondelmeyer provides a useful graphical comparison of the real world definition of "retail

pharmacy class of trade” with CMS’s artificial one. *See* Schondelmeyer Report, Exhibits 3F and 3G.

4. “Covered Outpatient Drug.”

A price paid for a drug may be included in AMP calculations only if the drug is a “covered outpatient drug.” *See* 42 U.S.C. § 1396r-8(k)(1)(A) (“the drug” included in the definition of AMP is the manufacturer’s “covered outpatient drug”). “Covered” means paid by the Medicaid program. The Social Security Act defines “covered outpatient drug.” That definition specifically excludes drugs provided to patients in connection with “physicians’ services” or “outpatient hospital services” or “renal dialysis.” 42 U.S.C. § 1396r-8(k)(3).⁵ Defendants are only authorized to use AMP to establish Federal Upper Limits for multiple source drugs, and a “multiple source drug “ must be a “covered outpatient drug.” *See id.* at §§

⁵ 42 U.S.C. § 1396r-8(k)(3) states, in full:

(3) Limiting definition. The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):

- (A) Inpatient hospital services.
- (B) Hospice services.
- (C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.
- (D) Physicians' services.
- (E) Outpatient hospital services.
- (F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.
- (G) Other laboratory and x-ray services.
- (H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological [product] used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C)) for such drug, biological product, or insulin.

1396r-8(e)(4)-(5), 1396r-8(k)(7)(A)(i); *see also* AMP Rule § 447.502 (limiting definition of “multiple source drug” to “a covered outpatient drug”).

The AMP Rule improperly includes in AMP calculations sales of drugs that are not covered outpatient drugs. The AMP Rule includes sales to physicians, sales to outpatient hospital pharmacies and clinics, and sales to dialysis centers. *See* AMP Rule § 447.504(g)(3), (8), (13). These drugs will ordinarily be provided to patients incident to physicians’ services or outpatient hospital services or renal dialysis. *See* Schondelmeyer Report at ¶¶ 101, 133, 160-61 (prescription drugs provided through these settings do not qualify as covered outpatient drugs and therefore should not be included in AMP calculations); *see also* 42 C.F.R. § 482.54 (Medicare condition of participation applicable to vast majority of hospitals say hospital outpatient services must be “integrated” with inpatient services). Therefore, it is inappropriate to include these sales in AMP calculations.

In addition, the AMP Rule includes sales to surgical centers, ambulatory care centers and mental health clinics. *See id.* at § 447.504(g)(8). Commenters explained that these drugs are ordinarily provided “incident to” physician’s services, but the Defendants nevertheless included these sales in AMP calculations. *See* AMP Rule Preamble, 72 Fed. Reg. at 39172, 39189; *see also* Schondelmeyer Report at ¶¶ 71, 97, 158.

5. Specific Transactions Included in the AMP Rule Do Not Meet the Statutory Definition of AMP.

The following specific transactions are improperly included in the AMP Rule because they are not prices paid to manufacturers by wholesalers for covered outpatient drugs distributed to the retail pharmacy class of trade.

A. *Sales to physicians (AMP Rule, §447.504(g)(13)).* These sales utterly fail the statutory test because physicians are neither wholesalers, nor retail pharmacies. Schondelmeyer Report at ¶¶ 175-76. The Defendants recognize this fact by excluding physicians from the

definition of “retail pharmacy” in the Medicare program. *See* 42 C.F.R. § 423.100. In addition, these sales do not qualify as sales of covered outpatient drugs. *See* 42 U.S.C. § 1396r-8(k)(3); Schondelmeyer Report at ¶ 101.

B. Direct sales to patients (AMP Rule, §447.504(g)(7)). Patients are neither wholesalers nor retail pharmacies. Schondelmeyer Report at ¶¶ 155-158. Therefore, this provision does not satisfy two parts of the statutory test for inclusion in AMP calculations.

The Defendants suggest that direct sales to patients may be included in AMP calculations where a manufacturer “retains ownership of the drugs” but hires a distribution company that “acts” like a wholesaler. AMP Rule Preamble, 72 Fed. Reg. at 39185; *see also id.* at 39148-49. This interpretation is fundamentally flawed for three reasons. First, the manufacturer “retains ownership,” so the distributor does not satisfy the Defendants’ own definition of “wholesaler.” *See* AMP Rule § 447.504(f) (a “wholesaler” is an entity to which the manufacturer “sells” drugs). Second, sales to patients are specifically excluded from federal and State definitions of “wholesale distribution”, so the distributor is not “acting” like a drug wholesaler in this situation. *See* 21 U.S.C. § 353(e); 21 C.F.R. § 205.3(f); 21 C.F.R. § 203.3 (cc)-(dd); Schondelmeyer Report at ¶ 156. Third, the situation described by the Defendants does not satisfy the statutory test for AMP because the drugs are not distributed to the retail pharmacy class of trade – they are distributed “directly” to the patient. *See* Schondelmeyer Report at ¶¶ 88, 157-58.

C. Sales to medical outpatient facilities (AMP Rule, §447.504(g)(8)). This provision of the AMP Rule includes sales to dialysis centers, surgical centers, mental health facilities, ambulatory care facilities, and physician clinics. These sales do not satisfy the statutory test for AMP calculations because they are not sales to wholesalers, and they are not sales of drugs distributed to the retail pharmacy class of trade. *See* Schondelmeyer Report at ¶¶ 159-60. These medical facilities provide drugs only in connection with medical services such as surgery,

dialysis, or mental health care. *Id.* at ¶ 161. In the Medicare program, the Defendants recognize that these facilities are distinct from, and not included in the definition of, retail pharmacies. *See* 42 C.F.R. § 423.100. In addition, these sales do not satisfy the statutory test for AMP calculations because they are not sales of covered outpatient drugs. *See* 42 U.S.C. § 1396r-8(k)(3); Schondelmeyer Report at ¶ 101.

D. *Sales to hospital pharmacies, clinics, and “affiliated entities” (AMP Rule, §447.504(g)(3)).* Including these sales violates the statutory AMP test because none of these entities is a wholesaler. Schondelmeyer Report at ¶¶ 142-43. The Defendants have recognized this fact for many years because they have in the past specifically excluded from AMP calculations all “direct sales to hospitals.” *See* AMP Rule Preamble, 72 Fed. Reg. at 39145, quoting National Rebate Agreement, 56 Fed. Reg. 7049 (Feb. 21, 1991).

This provision also violates the AMP test because these entities are not retail pharmacies. They are part of a structurally defined class of trade that is distinct from the retail pharmacy class of trade. Schondelmeyer Report at ¶¶ 133-134. Moreover, the general public cannot obtain prescriptions from these entities. *Id.* at ¶¶ 135-36.

Defendant CMS recognizes that these entities are not part of the retail pharmacy class of trade. In previous proposed AMP rules, Defendant CMS explained that hospitals “are not considered the retail pharmacy class of trade.” 60 Fed. Reg. 48442, 48462, 48487 (Sept. 19, 1995). In promulgating the recent Medicare drug benefit rules, the Defendants explained that “Examples of non-retail pharmacies include . . . hospital and other provider-based pharmacies.” 70 Fed. Reg. 4194, 4249 (Jan 28, 2005), promulgating 42 C.F.R. §423.100 (defining “retail pharmacy” to include only pharmacies where a patient can obtain covered drugs “without being required to receive medical services from a provider or institution affiliated with that pharmacy”).

Finally, including these transactions is inappropriate because they are not sales of “covered outpatient drugs.” *See* 42 U.S.C. § 1396r-8(k)(3); Schondelmeyer report at ¶¶ 101, 137.

E. *Sales to retail pharmacies (AMP Rule, §447.504(g)(5))*. Including these sales violates the statutory AMP test to the extent that they do not involve prices paid by wholesalers to manufacturers. Retail pharmacies are not generally licensed as wholesalers. *See* Schondelmeyer Report at ¶ 142. In fact, sales directly to retail pharmacies “bypass the wholesaler function.” *Id.* at ¶ 143. *See also* 21 U.S.C. § 353(e); 21 C.F.R. §§ 203.3, 205.3 (excluding from drug “wholesale distribution” traditional pharmacy practices such as dispensing drugs to patients and “intracompany transfers” of drugs between pharmacies).

F. *Sales to other manufacturers (AMP Rule, §447.504(g)(2))*. Manufacturers are not normally licensed as wholesalers, and the drugs they purchase are not necessarily distributed to retail pharmacies, so including these sales violates two parts of the statutory test for inclusion in AMP. *See* Schondelmeyer Report at ¶¶ 129-31. Both the statute and the AMP Rule specifically state that the term “manufacturer” “does not include a wholesale distributor of drugs or a retail pharmacy licensed under state law.” 42 U.S.C. § 1396r-8(k)(5); AMP Rule at § 447.502. The Defendants admit that including sales to manufacturers in AMP calculations is inappropriate and not in accordance with the law. *See* AMP Rule Preamble, 72 Fed. Reg. at 39200 (“... the DRA did not amend the definition of AMP, which continues to require that AMP be calculated with respect to the covered outpatient drug of a manufacturer based on the price paid to the manufacturer “by wholesalers for drugs distributed to the retail pharmacy class of trade.” *The DRA did not amend the AMP definition to include prices paid to the manufacturer by other manufacturers.*”) (emphasis added).

G. Sales to home infusion providers (AMP Rule, §447.504(g)(10)). These sales do not qualify for inclusion in AMP calculations because home infusion providers are neither wholesalers nor retail pharmacies. See Schondelmeyer Report at ¶¶ 162-64. The Defendants admit that “home infusion therapy pharmacies serve a defined population based on medical condition and are classified differently for the purpose of reimbursement,” which corroborates that specialty pharmacies do not serve the general public. See AMP Rule Preamble, 72 Fed. Reg. at 39176. The Defendants recognize that home infusion pharmacies are distinct from retail pharmacies in their Medicare drug benefit rules. See 42 C.F.R. § 423.120 (“retail pharmacy” includes only pharmacies where a patient may purchase prescription drugs “without being required to receive medical services from a provider or institution affiliated with that pharmacy”).

H. Sales to home health providers (AMP Rule, §447.504(g)(12)). These sales do not qualify for inclusion in AMP calculations because home health care providers are not wholesalers and they are not part of the retail pharmacy class of trade. See Schondelmeyer Report, ¶¶ 171-73. In particular, home health care providers do not serve the general public. Instead, they serve a specialized group of patients with special medical and service needs. *Id.* at ¶ 174.

I. Specialty pharmacy sales (AMP Rule, §447.504(g)(11)). These sales do not qualify for inclusion in AMP calculations because specialty pharmacies are neither wholesalers nor retail pharmacies. See Schondelmeyer Report at ¶¶ 166-67, 169. Specialty pharmacies do not serve the general public. Instead, they serve a small, usually an enrolled segment of the population with unique medical and drug needs. Schondelmeyer Report, ¶ 170; see also AMP Rule Preamble, 72 Fed. Reg. at 39176 (acknowledging “the fact that the [specialty] pharmacies

serve a client population characterized by specific medical conditions” but nevertheless asserting that they serve the general public).

J. Sales to mail order pharmacies (AMP Rule, §447.504(g)(9)). These sales should not be included in AMP calculations because mail order pharmacies are not normally wholesalers. See Schondelmeyer Report at ¶¶ 150-51 (“These mail order pharmacies do not generally function as, and are not generally licensed as, wholesalers”). In addition, these sales should not be included in AMP calculations because mail order pharmacies are not part of the retail pharmacy class of trade. The drug industry recognizes that mail order pharmacies are in a different “structural class of trade” from retail pharmacies, and they offer substantially reduced prices to mail order pharmacies that are not available to retail pharmacies. Schondelmeyer Report at ¶ 153.

The Defendants agree that mail order pharmacies are not “retail pharmacies” in a directly analogous situation. A Medicare drug benefit rule defines “retail pharmacy” as a “licensed pharmacy that is not a mail order pharmacy. . . .” 42 C.F.R. § 423.100; *see also* 42 C.F.R. § 423.120(a)(3) (mail order pharmacy is “non-retail”). The Defendants made this distinction “in light of those pharmacies’ different characteristics.” 70 Fed. Reg. 4194, 4253 (Jan. 28, 2005). The Defendants contradict their own Medicare definition of retail pharmacy by including mail order pharmacies in their Medicaid definition.⁶

⁶ Other agencies and the States also recognize the distinction between mail order pharmacies and retail pharmacies.

- o Defendant HHS’ Office of Inspector General concluded that mail order pharmacy sales should not be included in AMP calculations because mail order pharmacies were not in the retail pharmacy class of trade. See OIG, *Determining Average Manufacturer Prices For Prescription Drugs Under The Deficit Reduction Act Of 2005*, p. 4, A-06-06-00063 (May 2006).
- o The Federal Trade Commission has defined the mail order pharmacy market as distinct from the retail pharmacy market. See *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (FTC Aug. 2005) at <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>; *In the Matter of Rite Aid Corp. and The Jean Coultu Group* (June 2007 merger settlement) [documents at

Mail order pharmacies are not retail pharmacies because they do not normally serve the general public. Instead, they are only open to “enrolled populations in an insurance program, not the general public.” Schondelmeyer Report at ¶ 152. The Defendants were made aware of these “closed-door mail order pharmac[ies]” but they nevertheless continued to assert that “all” sales to mail order pharmacies are part of the retail market and are available to the general public. *See* AMP Rule Preamble, 72 Fed. Reg. at 39173. Finally, mail order pharmacies rarely serve Medicaid beneficiaries. Schondelmeyer Report at ¶ 152.

K. *Sales and Rebates To PBMs (AMP Rule, §447.504(g)(6))*. These rebates are not part of the “price paid to the manufacturer” for drugs. Rebates are paid by manufacturers to PBMs for services provided by the PBM, such as market share movement, preferred formulary status, or other services. PBM rebates “are compensation for the service provided, and are not a discount to the price.” Schondelmeyer Report at ¶ 148. Since PBM rebates do not reduce the price paid to the manufacturer for drugs, it is inappropriate to subtract the rebates from those prices when calculating AMP. *Id.* at ¶¶ 147-49.

In addition, these sales should not be included in AMP calculations because PBMs are not wholesalers. *Id.* at ¶ 145. The Defendants admit in no uncertain terms that PBMs are not wholesalers:

<http://www.ftc.gov/os/caselist/0610257/0610257.shtml>]; *In re: CVS Corp. and Revco* (August 1997 merger settlement) [documents at <http://www.ftc.gov/os/1997/08/index.shtml>].

- o The Tricare medical program for military families distinguishes between its “mail service pharmacy program” and its “retail pharmacy network” (which does not include mail order pharmacies). *See* 10 U.S.C. §§ 1074g, 1079; 32 C.F.R. § 199.21(c),(f).
- o The Census Bureau has adopted industry classification codes that place mail order pharmacies in a completely different class from “pharmacies and drug stores.” 66 Fed. Reg. 3826 (Jan. 16, 2001); *see* Census Bureau industry classification code 446110, available at <http://www.census.gov/epcd/naics02/def/ND446110.HTM>.
- o States license mail order pharmacies separately from retail pharmacies. Schondelmeyer Report at ¶ 105

We agree with the commenters that many of the sales to PBMs do not flow through wholesalers so the discounts received by PBMs generally do not affect the price actually realized. The distribution functions typically performed by wholesalers are different from the functions performed by PBMs. Furthermore, because rebates, discounts, or other price concessions obtained by PBMs are not passed on to the retail pharmacy class of trade, including PBMs in the definition of wholesalers would permit the inclusion of price concessions to which community retail pharmacies do not have access. Therefore, in Sec. 447.504(g), we are not classifying PBMs as wholesalers.

AMP Rule Preamble, 72 Fed. Reg. at 39192 (emphasis added).

L. GPO Fees (AMP Rule, §447.504(i)). The AMP Rule includes certain “administrative fees, service fees, [and] distribution fees” that will reduce AMPs. *See* AMP Rule § 447.504(i). These fees are often paid to entities such as group purchasing organizations (“GPOs”). According to CMS, fees paid by manufacturers to GPOs will be included in AMP calculations in some circumstances. *See* AMP Preamble, 72 Fed. Reg. at 39183-84. These fees must not be included in AMP calculations because they are not prices paid to manufacturers. These fees are paid by manufacturers, often to non-purchasers. Schondelmeyer Report at ¶¶ 193-94. As pointed out in the public comments to the AMP Rule, in many cases, such manufacturer fees are not paid to a wholesaler or other purchaser, but rather to “third parties like PBMs and GPOs that do not purchase or take possession of drugs (and for GPOs, do not even pay for drugs).” *See* AMP Rule Preamble, 72 Fed. Reg. at 39183.

In addition, these fees must not be included in AMP calculations because they involve transactions by non-wholesalers. GPOs are not wholesalers. *See* Schondelmeyer Report at ¶¶ 37, 194. The federal definition of drug “wholesale distribution” specifically excludes GPOs acting on behalf of their members. *See* 21 C.F.R. § 205.3(f).

M. Nominal Price Sales To “Any Entity” (AMP Rule, § 447.504(g)(4)). Including sales to “any entity” at nominal prices in AMP calculations is inappropriate. The “entity” that pays a nominal price for drugs is almost certainly not a wholesaler, and the drugs will almost certainly not be distributed to the retail pharmacy class of trade. *See* Schondelmeyer Report at

¶¶ 138-41. Manufacturers accept nominal prices from charities and from hospitals with physicians who are able to move patients to particular drugs. *Id.* at ¶¶ 139-40. As a result, nominal prices are paid by hospitals, not wholesalers or retail pharmacies. *See Id.*; AMP Rule Preamble, 72 Fed. Reg. at 39205 (citing Senate Finance Committee report).

N. *Rebates and Discounts "Associated With" Sales (AMP Rule, § 447.504(g)(14)).*

These rebates are paid by the manufacturer, and they are not necessarily paid to the purchaser of the drugs, so they are not "prices paid to the manufacturers." These rebates are payments for separate services such as moving market share, and are "not a discount to the price."

Schondelmeyer Report at ¶ 180. Because these rebates are not "prices paid to the manufacturers" they should not be included in AMP calculations. *Id.* at ¶¶ 179-80. In addition, these discounts and rebates should not be included in AMP calculations because they are not linked to sales to wholesalers. *Id.* at ¶¶ 179-80.

O. *Sales Reimbursed By Third Parties (AMP Rule, § 447.504(g)(15)).* This provision fails the statutory AMP test because these sales are included in AMP calculations regardless of whether the sales are to wholesalers. *See* Schondelmeyer Report at ¶ 182.

P. *Low Income Patient Programs (AMP Rule at § 477.504(h)(9), (12), (16), (17)).*

The AMP Rule purports to *exclude* from AMP calculations sales to manufacturer's "patient assistance programs," "[m]anufacturer coupons redeemed by a consumer," "manufacturer vouchers" and "[m]anufacturer-sponsored drug discount card programs." However, in some circumstances, the Defendants require manufacturers to include in AMP calculations sales associated with these programs. AMP Rule Preamble, 72 Fed. Reg. at 39187-89, 39226.

These transactions do not involve prices paid to manufacturers. The Defendants acknowledge that these programs often involve providing "free products" or "free samples" to patients. AMP Rule Preamble, 72 Fed. Reg. at 39187-88.

In addition, sales associated with these programs should not be included in AMP calculations because they include drugs that have not been sold to wholesalers for distribution to the retail pharmacy class of trade. Schondelmeyer Report at ¶¶ 183-92.

6. The AMP Rule Wrongly Mandates Inclusion of Virtually All Prices Without Requiring Evidence That the Prices Satisfy the Statutory Test.

The AMP Rule requires manufacturers to include prices paid by wholesalers in AMP calculations even if the manufacturers have no idea whether the drugs were distributed to the retail pharmacy class of trade. This is a clear violation of the statutory test for AMP calculations.

Under the statute, a drug price must be excluded from AMP calculations unless the drug is distributed to the retail pharmacy class of trade. The statute requires at least some evidence that the drug is “distributed to the retail pharmacy class of trade.” *See* 42 U.S.C. § 1396r-8(k)(1).

In contrast, the AMP Rule requires manufacturers to include in AMP calculations the prices they are paid for virtually all the drugs they sell, even if there is a complete absence of any evidence that the drugs were distributed to the retail pharmacy class of trade. The AMP Rule provides that all sales to “wholesalers” (defined as virtually all purchasers) must be included in AMP calculations unless the manufacturer has “adequate documentation” that proves the drugs were “subsequently sold” to an excluded entity. *See* AMP Rule § 447.504(g)(1).

For example, the Defendants specifically exclude long-term care facilities from the retail class of trade. AMP Rule at § 447.504(h)(6). However, a commenter pointed out that in some situations it is “impossible” for a manufacturer to determine whether drugs were sold to a long-term care facility or to the retail pharmacy class of trade. AMP Rule Preamble, 72 Fed. Reg. at 39190. The Defendants responded that “[w]here a manufacturer does not have adequate

documentation to substantiate whether these drugs are dispensed to a long-term care facility or to the general population, the manufacturer should include all of the sales in AMP.” *Id.*⁷

Importantly, the AMP Rule does not require that manufacturers make any effort whatsoever to obtain “adequate documentation.” In fact, the Defendants readily concede that manufacturers often will not have adequate documentation to make these determinations because they may not know which drugs are distributed by wholesalers to the retail pharmacy class of trade. AMP Rule Preamble, 72 Fed. Reg. at 39146-47, 39190, 39193.

Moreover, manufacturers have a financial incentive to avoid obtaining this adequate documentation. Manufacturers can lower the rebates they pay to States by including in AMP calculations low-priced sales that decrease AMP. *See Schondelmeyer Report* at ¶¶ 197-99; *see also* AMP Rule Preamble, 72 Fed. Reg. at 39146 (“Including these lower prices would decrease the AMP, decreasing manufacturers’ rebate liability.”)

In sum, before drug prices may be included in AMP calculations the statute requires proof, or at least some evidence, that the purchased drugs are distributed to the retail pharmacy class of trade. The AMP Rule’s “adequate documentation” provision eliminates this statutory requirement. Instead, the AMP Rule requires manufacturers to include almost all sales in AMP calculations, unless the manufacturers have written evidence that the drugs were not distributed to the retail pharmacy class of trade. The AMP Rule thus violates a crucial part of the statutory test for AMP calculations.

7. AMP Website

The same section of the Social Security Act that defines AMP also requires the Secretary of HHS to “disclose (through a website accessible to the public) average manufacturer prices.”

⁷ The only exception appears to be sales to hospitals, which are excluded from AMP calculations unless the manufacturer has “adequate documentation” that the drugs sold were used in the outpatient setting. *Id.* at § 447.504(g)(3).

42 U.S.C. § 1936r-8(b)(3)(D)(v). The Defendants announced their plan to post on a public website the AMP data calculated pursuant to the AMP Rule. AMP Preamble at 39146, 39213.

As discussed in detail above, the AMP Rule does not abide by the Social Security Act's definition of AMP. As a result, the data calculated pursuant to the AMP Rule will not qualify as "average manufacturer prices" as defined by the statute. The Defendants will not be in compliance with the statute if they post that data, rather than true AMP data, on a website.

This is not a mere academic issue. States and other payers will use the Defendants' website as a basis for establishing reimbursement rates for retail pharmacies. *See* AMP Rule Preamble, 72 Fed. Reg. at 39146; Schondelmeyer Report at ¶¶ 206-10. Similarly, consumers will compare the prices they pay to the AMP data. Schondelmeyer Report at ¶ 207-08. Posting flawed data that the Defendants inaccurately call AMP will mislead and confuse these audiences, resulting in inappropriately low payment rates to retail pharmacies. It is vitally important that the data posted on a public website accurately reflect what they claim to be – the average price paid to manufacturers by wholesalers for outpatient drugs distributed to retail pharmacies.

Based upon the foregoing, the Plaintiffs have shown a substantial likelihood of success in proving that Defendants violated the Social Security Act by including in AMP calculations many transactions that do not satisfy the four-part statutory test for AMP.

C. The Final Rule Fails to Follow the Statutory Requirements for Defining What is a Multiple Source Drug.

The Social Security Act authorizes the Defendants to establish Federal Upper Limits on Medicaid reimbursement "for each multiple source drug." 42 U.S.C. § 1396r-8(e)(4). That same Section of the statute establishes a very specific test to determine whether a drug qualifies as a multiple source drug. According to the statute, a drug is a multiple source drug in a particular State only if at least one other equivalent drug product "is sold or marketed in the State. . . ." *See* 42 U.S.C. § 1396r-8(k)(7)(A)(i)(III). The statute explains that "a drug product is considered to

be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.” 42 U.S.C. § 1396r-8(k)(7)(C)(iii).

These statutory provisions establish two specific tests for qualifying as a multiple source drug that is “sold or marketed in the State.” First, the drug product must appear in a “published national listing of average wholesale prices selected by the Secretary.” Second, the listed drug product must be “generally available to the public through retail pharmacies in that State.” This statutory test helps ensure that retail pharmacies in each State are able to buy and dispense the multiple drug products that are used to set the Federal Upper Limits. The Defendants completely ignore these statutory tests.

1. Defendants Ignore The Statute’s “Published National Listing” Requirement.

In 1990, Congress added the “published national listing” requirement to the Social Security Act. *See* Omnibus Budget Reconciliation Act of 1990, P.L. 101-508, Section 4401. The DRA did not delete, amend, or otherwise change this requirement.

The rules in place before the AMP Rule provided that the drug products used to set Federal Upper Limits had to be listed in “published compendia of cost information for drugs available for sale nationally.” 42 C.F.R. § 447.332(a)(ii) (1986), *published at* 52 Fed. Reg. 28648, 28658 (July 31, 1987). Similarly, the proposed version of the AMP Rule included a published national listing requirement. *See* 71 Fed. Reg. 77173, 77199 (Dec. 22, 2006) (proposed § 447.514(a)(1)(ii) provided that the drug products must be listed in “published compendia of cost information for drugs available for sale nationally.”).

However, in an abrupt reversal, this requirement was deleted from the final version of the AMP Rule. *See* AMP Rule, § 447.514. The Defendants acknowledge that they reversed their longstanding position on this issue. *See* Preamble to AMP Rule, 72 Fed. Reg. at 39154-55.

However, the Defendants never addressed the fact that the Social Security Act requires the Secretary to ensure that the drug products appear in a “published national listing of average wholesale prices selected by the Secretary.”

The statute’s “published national listing” requirement should not be read as mere surplus language. *See United States v. Menasche*, 348 U.S. 528, 539 (1955), *quoting NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 30 (1937) and *Montclair v. Ramsdell*, 107 U.S. 147, 152 (1883) (recognizing that the “. . . cardinal principle of statutory construction is to save and not to destroy. It is [a Court’s] duty to give effect, if possible, to every clause and word of a statute.”). Nor may it be ignored by the Defendants. The Plaintiffs are substantially likely to succeed in their claim that the Defendants have not complied with this statutory requirement.

2. Defendants Ignore The State Availability Requirement.

The Defendants also ignore the requirement that Federal Upper Limits may be applied in a State only if they are based on drug products that are available “in the State.” This test was added to ensure that the drug products used to calculate Federal Upper Limits on reimbursement are available for purchase in each State where the Federal Upper Limits will be applied. When it adopted the State availability requirement in OBRA ‘90, the Senate Committee on Energy and Commerce wrote that “The Committee is concerned that the methodology for determining upper payment limits does not take into account the availability of generic products throughout the country, which may lead to upper payment limits that are unreasonably low.” 136 Cong. Rec. S15658 (1990).

For decades, both Congress and the Defendants recognized the importance of this issue. As far back as 1972, Congress established a system for establishing upper limits on Medicaid reimbursement for multiple source drugs that required the upper limits to be based on charges for drug products that were “widely and consistently available in a locality.” *See Social Security*

Act Amendments of 1972, Pub. L. 92-603, § 224, 86 Stat. 1395 (Oct. 30, 1972). Regulations issued by HHS (then known as the Department of Health, Education and Welfare) included this requirement, and added that different upper limits on reimbursement would be established in particular “localities” if it appeared that a drug “is or will be unavailable to providers in one or more localities” at the price used to set the upper limit on reimbursement. *See* 45 C.F.R. § 19.5, published at 40 Fed. Reg. 32302 (July 31, 1975).

Thus, when Congress enacted the State availability requirement in 1990, it did so based on a long history of recognizing the importance of ensuring the availability of multiple source drug products used to calculate upper limits on reimbursement. The State availability requirement has been a fixture of the Social Security Act since it was added by Congress in 1990. *See* Omnibus Budget Reconciliation Act of 1990, Pub. L. 101-508, § 4401.

The DRA did not delete, amend, or affect this State availability requirement. On the contrary, the DRA reflects Congress’ continued recognition of the importance of ensuring the availability of drug products used to set Federal Upper Limits on reimbursement. The DRA authorizes the Secretary to hire a vendor to inform the Secretary about new multiple source drug products only if the new products are “generally available.” *See* Deficit Reduction Act of 2005, Pub. L. 109-171, § 6001, adding Social Security Act § 1927(f)(1)(A)(ii).

In 1995, the Defendants issued proposed rules for calculating Federal Upper Limits for multiple source drugs. Those proposed rules defined “multiple source drug” as drug products that are “sold or marketed in the State during a rebate period.” *See* 60 Fed. Reg. 48442, 48483 (Sept. 19, 1995). The Defendants also limited AMP calculations to prices paid to manufacturers for the drug “in the State” by wholesalers. *Id.* at 48487. Although those proposed rules were never finalized, they demonstrate that the Defendants were well aware of the State availability test and were able to distinguish between “in the State” and “in the United States.”

The AMP Rule's definition of "multiple source drug" is strikingly similar to the 1995 proposed rule's definition and the statute, with one telling exception: the AMP Rule drops the statutory requirement that the drug must be "sold or marketed in the State" and replaces it with language that the drug must be "sold or marketed in the United States. . . ." *See* AMP Rule, § 447.502. The AMP Rule disregards the statute's State availability test and instead establishes nationwide Federal Upper Limits for drugs so long as the drugs are sold or marketed somewhere in the United States.

The Defendants were alerted to the issue of ensuring availability of multiple source drug products in each State, but they declined to include such protections. *See* AMP Rule Preamble, 72 Fed. Reg. at 39215-16. The AMP Rule ignores the clear statutory language and replaces it with the Defendants' own policy choice. Defendants clearly cannot do this. The Supreme Court has repeatedly stated that "estimations . . . of desirable policy cannot alter the meaning" of federal statutes. *MCI Telecomms. Corp. v. AT & T Co.*, 512 U.S. 218, 234 (1994). "[S]uch considerations address themselves to Congress, not to the courts." *Id.* (citing *Armour Packing Co. v. United States*, 209 U.S. 56, 82, 28 S. Ct. 428, 435 (1908)); *see also*, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000) ("[N]o matter how 'important, conspicuous, and controversial' the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress.")

3. The Defendants Fail To Ensure Availability Through Retail Pharmacies.

One crucial aspect of the State availability test is that the drug products must be generally available to the public in each State "through retail pharmacies." The AMP Rule fails to satisfy, or even address, this aspect of the State availability test.

The Defendants' prior rules for calculating Federal Upper Limits on reimbursement did address the availability of drug products through retail pharmacies. The rules in existence for two decades before the AMP Rule provided that Federal Upper Limits would be based on multiple source drug products "that can be purchased by pharmacists" in quantities commonly purchased by pharmacists. *See* 42 C.F.R. § 447.332(b) (1987), published at 52 Fed. Reg. 28648, 28658 (July 31, 1987). The Defendants proposed to keep this requirement in 1995. *See* 60 Fed. Reg. 48442, 48481 (Sept. 19, 1995). However, in the AMP Rule the Defendants reversed course and completely dropped any requirement that the drug product used to set the Federal Upper Limit must actually be generally available to the public in each State "through retail pharmacies."

This is important because some drug products that would otherwise satisfy the test for multiple source drugs are not generally available to the public through retail pharmacies. These drug products are available through other medical providers (*e.g.*, physicians, hospitals, or clinics), but not retail pharmacies. Schondelmeyer Report at ¶¶ 202, 204-05. Therefore, the situation that Congress attempted to avoid with the State availability test is exactly what will occur: inappropriately low Federal Upper Limits will be established based upon prices for drugs that are not available to retail pharmacies.

Another situation that arises is when regional manufacturers, wholesalers and distributors sell drugs in parts, but not all, of the nation. *Id.* at ¶ 202-03. These products may have low AMPs that are used to calculate Federal Upper Limits, even though pharmacies in other states cannot purchase those products at those low prices. *Id.* at ¶¶ 203.

That is why the State Medicaid directors specifically asked the Defendants to address this issue in the AMP Rule. Comments submitted by the National Association of State Medicaid Directors provided that "States ask that CMS consider the variations in prices and availability

across states.” The State Medicaid Directors recommended that CMS establish a process for adjusting Federal Upper Limits based on variations in drug availability and prices between States:

We wish to offer for CMS' consideration the possibility of creating an appeals process to allow pharmacies, drug wholesalers, and states to report situations whereby prescription drugs are not available or not available at the prices listed under the AMP-based FUL. For example, rural pharmacies may not have access to the same pricing available to larger markets or mail order pharmacies. Confirmed reports could result in CMS raising or suspending a FUL.

See Letter to CMS from National Association of State Medicaid Directors and American Public Health Services Association, p. 2-3 (Feb. 20, 2007), available at <http://www.cms.hhs.gov/eRulemaking/ECCMSR/list.asp>.

In sum, the Defendants have failed to ensure that Federal Upper Limits are established only for multiple source drugs, as defined by the statute. Rather than abide by the statute’s State-based approach, the Defendants have opted for a nationalized approach that ignores variations in the availability and prices of drugs in different States. The Plaintiffs are substantially likely to succeed in their claim that the Defendants have not complied with this statutory requirement.

D. Defendants Improperly Apply The Federal Upper Limits to Non-Equivalent Drug Products.

The Social Security Act clearly and repeatedly provides that the Federal Upper Limits on reimbursement for drugs apply only to “equivalent” drug products. The Defendants have violated the statute by applying the Federal Upper Limits to non-equivalent drug products.

1. All The Relevant Statutory Provisions Clearly Apply Only To “Equivalent” Drug Products.

The Social Security Act authorizes the Defendants to establish Federal Upper Limits on Medicaid reimbursement only for “equivalent” multiple source drugs. Specifically, the statute provides that “the Secretary shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more (or, effective January 1, 2007, two or

more) products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit.” 42 U.S.C. § 1396r-8(e)(4).

The statute also creates a process for identifying new drug products that may justify new Federal Upper Limits. Significantly, the statute limits identification of a new drug product only to “a drug product that is therapeutically and pharmaceutically equivalent and bioequivalent....” Id at § 1396r-8(f)(1)(A)-(B). *See also* AMP Rule Preamble, 72 Fed. Reg. at 39155 (Social Security Act interpreted to provide that “the Secretary, after receiving notification that a therapeutically equivalent drug product is generally available, shall determine within seven days if that drug product should have a FUL”).

The statute even defines “multiple source drug” exclusively with reference to “equivalent” drug products. The Social Security Act provides that a multiple source drug exists only if there is “at least one other drug product” which is “therapeutically equivalent (under the Food and Drug Administration’s most recent publication of “Approved Drug Products with Therapeutic Equivalence Evaluations”). . . .” 42 U.S.C. § 1396r-8(k)(7).

The FDA publication referenced in the statute is known as the “Orange Book.” Drug products that the Orange Book identifies as equivalent are referred to as “A-rated” drug products. In contrast, drug products that the FDA “considers not to be therapeutically equivalent” are referred to as “B-rated” drug products. *See* Orange Book, 27th Ed. (2007), available at <http://www.fda.gov/cder/orange/default.htm>; AMP Rule Preamble, 72 Fed. Reg. at 39154-55.

2. The Defendants Violated The Statute By Applying Federal Upper Limits to Non-Equivalent Drug Products.

Despite these statutory provisions, the Defendants have stated in no uncertain terms that they plan to apply Federal Upper Limits to “B-rated” drug products that are not equivalent to the drug products that were used to set the Federal Upper Limit. The Defendants wrote that “[w]e

proposed that the FUL will be established, as per section 1927(e)(4) of the Act, only using an “A” rated drug. However, we proposed to continue our current practice of applying the FUL to all drug formulations, including those drug versions not proven to be therapeutically equivalent, (for example, B-rated drugs).” AMP Rule Preamble, 72 Fed. Reg. at 39155. In response to a comment objecting to this approach, the Defendants reiterated their decision to apply the Federal Upper Limits to non-equivalent B-rated drug products. *Id.* at 39215.

The Defendants’ policy of applying the Federal Upper Limit to non-equivalent B-rated drugs violates the plain meaning of the Social Security Act. The statutory provisions discussed above clearly and repeatedly limit the Federal Upper Limits only to equivalent “A-rated” multiple source drug products, *i.e.*, those that are “therapeutically equivalent.” Applying Federal Upper Limits to non-equivalent B-Rated drugs will harm retail pharmacies by imposing additional reimbursement limits on retail pharmacies beyond the many reimbursement limits that apply under other provisions of federal and state law.

The Defendants acknowledge that they decided to apply the Federal Upper Limits to B-rated drugs for a purely financial reason. The Defendants stated that “We believe it is appropriate to apply the Federal Upper Limit to B-rated drugs in order not to encourage pharmacies to substitute B-rated drugs to avoid the FUL in the case where B-rated drugs would be excluded from the FUL.” *Id.* at 39155. *See also id.* at 39215 (“To do otherwise may encourage pharmacies to substitute B-rated drugs to avoid the FUL.”). Financial concerns are not a legitimate basis for ignoring a statutory requirement. *See Tennessee Valley Authority v. Hill*, 437 U.S. 153, 194 (1978) (holding that granting an injunction against the operation of a newly-constructed dam, which would have destroyed the habitat of the endangered snail darter fish, was appropriate despite the loss of millions of dollars of public funds spent on construction, and reasoning that “Congress has spoken in the plainest of words, making it abundantly clear

that the balance has been struck in favor of affording endangered species the highest of priorities....”).

Moreover, the Defendants financial concerns are completely unfounded because it is almost always illegal under state law for pharmacists to substitute B-rated drugs, especially for financial reasons. *See, e.g.*, D.C. Code §78-803.05. Beyond the statutes, pharmacists have a common law duty to fill prescriptions accurately, and pharmacists can be held liable for substituting a drug product that is not equivalent to the prescribed drug product. *Compare Bichler v. Willing*, 58 A.D.2d 331, 333, 397 N.Y.S.2d 57, 58 (NY App. Div. 1st Dep’t 1977) (dismissing negligence case against pharmacists where there was an “absence of any showing of a difference” between the prescribed drug and the therapeutically equivalent drug dispensed by the pharmacist); *with Henry v. Mylan Pharms, Inc.*, 2005 WL 2101049, CCH Prod. Liab. Rep. (CCH) P 17300 (W.D. Mo. Aug. 31, 2005) (refusing to dismiss claim that pharmacy improperly substituted generic drug product that was not equivalent to prescribed drug product); *Tadrus v. Missouri Bd of Pharmacy*, 849 S.W.2d 222, 227-28 (Mo. Ct. App. 1993) (pharmacist’s license suspended for improper generic substitutions; brand name drugs were prescribed and “[t]here was no equivalent generic drug for either, according to the [State formulary].”)

Based upon the foregoing, Plaintiffs have shown that they have a substantial likelihood of success in proving that Defendants violated the Administrative Procedure Act by applying FULs to non-equivalent drug products, in violation of the Social Security Act.

II. Plaintiffs Will Suffer Irreparable Harm Absent An Injunction.

The AMP Rule “will result in substantial loss, and even closures, for a number of pharmacies.” Schondelmeyer Report at ¶¶ 31, 226. The loss of 10,000 to 12,000 urban and rural pharmacies – 20 percent of all retail pharmacies – is expected. *Id.* Simply increasing other

prices or refusing to participate in the Medicaid program is not an option for many of these pharmacies. Schondelmeyer Report at ¶¶ 227.

The reason for this tremendous impact is that reimbursement rates for generic drugs will be cut by a staggering 78.7%. *Id.* at ¶ 221. Reimbursement rates actually will be substantially below the costs that retail pharmacies pay for those drugs. *Id.* at ¶¶ 28, 213-14, 223. Government studies have found that reimbursement for drugs will be cut well below the prices that retail pharmacies pay for drugs. *See* OIG, *Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program*, OEI-03-06-00400 (June 2007) (A copy of which is attached as Exhibit B); GAO, *Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs*, GAO-07-239R (Dec. 22, 2006) (A copy of which is attached as Exhibit C). No company can be expected to stay in business while operating at a loss. Reimbursement cuts were expected as a result of the DRA, but the AMP Rule greatly exacerbates those cuts by improperly including in AMP calculations drug sales prices that are much lower than the prices paid by retail pharmacies. *Id.* at ¶ 234. Courts have found irreparable harm in such situations. “[E]conomic loss may constitute irreparable harm where the loss threatens the very existence of the movant’s business.” *World Duty Free Americas, Inc. v. Summers*, 94 F. Supp. 2d 61, 67 (D.D.C. 2000).

The AMP website will also cause irreparable injury. *See* Schondelmeyer Report at ¶¶ 204-07. Once incorrect and misleading AMP data are made public on a website, it will be impossible to “un-ring the bell.”

In addition, the injuries suffered by pharmacies will be irreparable because they cannot be repaired by this Court. If the AMP Rule is not enjoined, but is later found to be unlawful, Plaintiffs’ members will not be able to recover underpaid Medicaid costs because the federal government enjoys sovereign immunity. Plaintiffs’ members also cannot simply raise other

prices or recover other losses generated by the AMP Rule, e.g., lost business due to reduced hours, services, and stores. Schondelmeyer Report at ¶¶ 227-28. These losses are irreparable. The Court has recognized that “admittedly economic” injury to a plaintiff amounts to irreparable harm if “no adequate compensatory or other corrective relief” could be provided at a later date. *Bracco Diagnostics v. Shalala*, 963 F. Supp. 20, 29 (D.D.C. 1997)(issuing injunction against Secretary of HHS). See also *Prairie Band of Potawatomi Indians v. Pierce*, 253 F.3d 1234, 1251 (10th Cir. 2001) (because “monetary relief might not be available to [plaintiff] because of the state’s sovereign immunity,” harm to plaintiff was irreparable); *National Medical Care, Inc. v. Shalala*, 1995 WL 465650 (D.D.C. June 6, 1995) (because plaintiff would be unable to recover against the government even if it subsequently prevailed on the merits, a preliminary injunction was proper).

III. Defendants Will Not Be Harmed By a Preliminary Injunction.

There is no harm, other than delay, that will inure to Defendants if the AMP Rule is enjoined. The Defendants have already delayed using AMP to calculate Federal Upper Limits for eleven months, and they have delayed implementing the AMP website for seventeen months. DRA § 6001(a), (2), b)(1). A temporary delay to give the Court sufficient time to review the merits of this case will not harm the Defendants.

A delay in implementing the AMP Rule clearly will not impede the Defendants from providing Medicaid covered prescription drugs to beneficiaries in accordance with the law. In fact, given that thousands of pharmacies are expected to close as a result of the AMP Rule, delaying the AMP Rule will help ensure that the Medicaid program continues to provide medications as intended.

Case law supports issuing an injunction where the only injury to the defendant agency is delay. See *International Long Term Care v. Shalala*, 947 F. Supp. 15 (D.D.C. 1996) (delay in

administrative process was inadequate basis for denying preliminary injunction to stop Secretary of HHS from terminating a nursing home's participation in the Medicare program); *DSE, Inc. v. United States*, 3 F. Supp. 2d 1464, 1472 (D.D.C. 1998) (issuing injunction despite resulting delay in performing a government contract); *Nat'l Treasury Employees Union v. U.S. Dep't of Treasury*, 838 F. Supp. 631, 640 (D.D.C. 1993).

IV. The Public Interest Favors A Preliminary Injunction.

A preliminary injunction will protect the public interest. If the AMP Rule is implemented, the public will be substantially harmed by the potential closure of 10,000 to 12,000 retail pharmacies. Schondelmeyer Report at ¶¶ 31, 226. Medicaid patients and all Americans depend on retail pharmacies for basic medicinal needs. *Id.* at ¶¶ 32-33, 38.

In addition, it is not in the public interest to allow the Defendants to post misleading and confusing AMP data on a public website. *Id.* at ¶¶ 206-08. The public interest will also be served by an injunction that prevents the Defendants from misleading and confusing the public by posting flawed AMP data on a public website. *Id.*

More fundamentally, the Defendants' failure to abide by the clear language of the Social Security Act in issuing and implementing the AMP Rule is contrary to the interest of the public. It is well settled in the D.C. Circuit that there exists "a strong public interest in requiring an agency to act lawfully, consistent with its obligations under the APA . . ." *Bracco*, 963 F. Supp. at 30. Consequently, it is in the public interest that an agency be enjoined from acting unlawfully. *See, e.g., Clarke v. Office of Fed. Hous. Enter. Oversight*, 355 F. Supp. 2d 56, 66 (D.D.C. 2004) (noting a "substantial public interest" in ensuring that a federal agency "acts within the limits of its authority"); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (1998)(affirming preliminary injunction based in part on the public interest in the faithful execution of the laws); *Nobby Lobby, Inc. v. City of Dallas*, 970 F.2d 82, 93 (5th Cir. 1992)

(approving the district court's conclusion that "the public interest always is served when public officials act within the bounds of the law and respect the rights of the citizens they serve").

Enjoining the AMP Rule will also save the public money. If the public has reduced access to pharmacies then the resulting decline in compliance with doctors' prescriptions will result in increased utilization of much more expensive hospital and physician services. In addition, the AMP Rule will encourage utilization of more expensive brand name drugs, which will actually increase overall drug expenditures. Schondelmeyer Report at ¶ 223.⁸ At any rate, it is inappropriate to elevate the potential benefits of unlawful conduct over the public interests of faithful application of the law. *See Mova Pharm.*, 140 F.3d at 1066 (upholding preliminary injunction issued in favor of a drug manufacturer that enjoined the FDA from permitting a competitor's generic drug to reach the market, where "the public's interest in the 'faithful application of the laws' outweighed its interest in immediate access to [the competitor's] generic product.")

CONCLUSION

The Defendants' total disregard for the clear intent of Congress when they promulgated the definition of AMP and the method for establishing and applying Federal Upper Limits is striking:

- (1) Defendants included a significant number of transactions in the calculation of AMP that have nothing to do with the price paid to manufacturers by wholesalers for covered out patient drugs distributed to the retail pharmacy class of trade;
- (2) Defendants ignored the statutory requirement that a multiple source drug used to establish an Federal Upper Limit must be available for dispensing by a retail pharmacy within each state where the Federal Upper Limit will be applied; and

⁸ State Medicaid agency directors noted that the proposed AMP Rule "could discourage generic dispensing and have the unintended effect of increasing brand utilization and Medicaid costs." *See Letter to CMS from National Association of State Medicaid Directors and American Public Health Services Association*, p. 2 (Feb. 20, 2007), available at <http://www.cms.hhs.gov/eRulemaking/ECCMSR/list.asp>

- (3) Defendants ignored the statutory requirement that the Federal Upper Limits only apply to "therapeutically equivalent" drugs.

This clear disregard of the statutory language and congressional intent requires that this Court not grant any deference to the AMP Rule. This Court should grant Plaintiffs' motion for preliminary injunction because NACDS and NCPA have clearly demonstrated that they have a likelihood of success on the merits; their members will suffer irreparable harm if an injunction does not issue; the Defendants cannot show that they would suffer any harm; and the public interest favors entering the injunction.

Respectfully submitted,

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